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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,943

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Andreas Reinmann

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05/01/2008

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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,943	Applicant(s) REINMANN ET AL.	
	Examiner MATTHEW F. DESANTO	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,10,12,13,15,17-34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,10,12,13,15,17-34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34, and 36 are rejected under rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. With regards to claims 1, 8, 17, 18, 22, 26, 36 are indefinite and ambiguous because of the claim limitation of a space being elastic, porous but non-permeable space. The contradiction of porous and non-permeable is the first issue since an element is not capable of being both. Therefore the examiner interprets this limitation as being a porous space.

4. With regards to the claims and the limitation of "being a passage not penetrable by the cannula" is also unclear since the claim recites a space and then seems to limit the claim by stating the space is a filled space or not penetrable by the cannula thus making the claim unclear as to whether a space exists or the space is filled with a second material with the given characteristics in the claims (which is absent from the specification). Therefore the examiner is confused because if the space is filled this would cause an issue as to whether there is a passageway.

5. The examiner would further like to note that the generally material of the claimed invention is an elastic material which would be penetrable by a sharp pointed cannula

and is once again unclear how the membrane would be able to be impenetrable by a cannula if sufficient force was applied to the cannula.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behnke et al. (USPN 5,520,641) in view of Paul, JR. (US Pub 20010041872).

Behnke discloses a membrane-cannula combination for biological applications, said combination comprising a cannula (C) for conveying a fluid, a casing (20, 24, 30), and a membrane (126) accommodated by said casing and comprising an elastic membrane material through which a passage is formed, into which said cannula can be inserted, wherein said passage is expanded by inserting the cannula and said membrane material presses against the casing, generally perpendicularly relative to the passage, and elastically presses against the inserted cannula such that the membrane material surrounds the cannula in a seal; wherein e) the passage and the cannula exhibit different cross-sectional shapes relative to each other before the cannula is inserted and one of the passage or the cannula has an elongated cross-sectional area (see figures 1, 2, 4, 6-9, and entire reference), but fails to disclose the specific shape of the openings in the membrane.

Paul, Jr discloses a medical fluid flow control membrane that has at least one perforation that can have a circle or oval shape (para [0052]). When the seal perforation is oval, the membrane will have “an increasing cross section from the first seal face to the second seal face” (paragraph [0052]).

Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Behnke with the teachings of Paul, Jr. because Paul, Jr. teaches the added benefit of modifying the shape of the perforation in the medical device membrane, so that the perforation in the membrane will have an increased cross section as well as other added benefits that were taught by Paul, Jr. (Paul Jr. para [0052]).

The examiner would also like to note that there is case law that further supports this rejection based on the obviousness of modifying a device in view of a shape.

8. Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (USPN 6,210,377), and further in view of Paul, JR. (US Pub 20010041872).

Ouchi discloses a membrane-cannula combination for biological applications, said combination comprising a cannula for conveying a fluid, a casing (2600); c) and a membrane (2721P, figure 86) accommodated by said casing and comprising an elastic membrane material through which a passage is formed, into which said cannula can be inserted, wherein said passage is expanded by inserting the cannula and said membrane material presses against the casing, generally perpendicularly relative to the

passage, and elastically presses against the inserted cannula such that the membrane material surrounds the cannula in a seal; wherein the passage and the cannula exhibit different cross-sectional shapes relative to each other before the cannula is inserted and one of the passage or the cannula has an elongated cross-sectional area (see figures 22, 27, 78-88, and Columns 15,16, & 27-29), but fails to disclose the specific shape of the openings in the membrane.

Paul, Jr discloses a medical fluid flow control membrane that has at least one perforation that can have a circle or oval shape (para [0052]). When the seal perforation is oval, the membrane will have “an increasing cross section from the first seal face to the second seal face” (paragraph [0052]).

Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Ouchi with the teachings of Paul, Jr. because Paul, Jr. teaches the added benefit of modifying the shape of the perforation in the medical device membrane, so that the perforation will have an increased cross section as well as other added benefits (Paul Jr. para [0052]).

The examiner would also like to note that there is case law that further supports this rejection based on the obviousness of modifying a device in view of a shape.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are not persuasive.

10. Applicant argues that the membrane comprises an "elastic, porous but non-permeable space," which is an ambiguous limitation due to the contradiction of porous

and non-permeable as well as the contradiction of a space being non-permeable. Due to this issue the examiner interpreted the claims as previously presented and that the space was a porous space thus leading to an opening or a hollow space.

11. With regards to the language of "compressible space not penetrable by a cannula formed from porous but non-permeable space" the examiner interpretation is much different then applicant's because the elastic material would be capable of being pierced by a cannula and thus is unclear how the membrane wouldn't be able to be penetrated by the cannula. The examiner would also like to note that the language could be interpreted as being fully closed and thus any part of the membrane that doesn't have a longitudinal opening would be considered part of the "compressible space that is not penetrable" by the cannula.

12. If applicant would like a telephonic interview in order to expedite the prosecution the examiner would be more than happy to arrange a time to do so.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto
April 28, 2008

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763